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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,206	12/17/2008	John W. Babich	346715-0632 NATL	7163
48329	7590	03/21/2011		
FOLEY & LARDNER LLP 111 HUNTINGTON AVENUE 26TH FLOOR BOSTON, MA 02199-7610			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			03/21/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,206	BABICH ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-28 and 52-84 is/are pending in the application.
- 4a) Of the above claim(s) 52-80 and 82-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-28 and 81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>see attachment</u> . | 6) <input type="checkbox"/> Other: _____ |

Information Disclosure Statements Attached: 1/24/11; 11/4/10; 10/13/10; 5/27/10; 5/17/10; 4/20/10; 11/25/09; 9/3/09; 3/26/09; & 2/7/07

/D. Jones/ 3/17/11
Primary Examiner
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ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 8/11/06 wherein the specification was amended; claims 1-25 and 29-51 were canceled; and claims 81, 82, and 84 were amended.

Note: Claims 26-28 and 52-84 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to bis(heteroaryl) compounds and uses thereof as set forth in independent claims 26, 52, 56, 63, and 71.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election without traverse of Group I (claims 26-28 and 81) in the reply filed on 2/1/11 is acknowledged. Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

In addition, the Examiner acknowledges Applicant's election of the species of Formula C wherein L = quinolinyl, R = (CH₂)₄CH(NH₂)(COOH); Z = COOH; m = 1; and n = 1. Initially, Applicant's elected species was searched. However, since no prior art was found to reject Applicant's elected species, the search was expanded to that wherein L = quinolinyl; R = H; n = 0; m = 0; and Z = substituted 2-(carboxyl)heteroaryl group. The search was not further expanded because prior art was found which could be used to reject the claims.

WITHDRAWN CLAIMS

4. Claims 52-80 and 82-84 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

112 FIRST PARAGRAPH REJECTION (Written Description)

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 26-28 and 81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to the ligands for G-protein coupled receptors that are encompassed by the instant invention. Applicant is reminded that while a generic claim may define the boundaries of a vast genus of chemical compounds (i.e., ligands for a G-protein coupled receptor), the question may still remain whether the specification demonstrates that Applicant invention species sufficient to support a claim to a genus. In this particular instance, the issue is

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especially acute with genus claims that use functional language to define the boundaries of a claimed genus. Thus, the claims are directed to a desired result (i.e., the compound has to be a functional ligand for a G-protein coupled receptor) wherein specific species that achieve that result are not disclosed. However, one is reminded that the specification must demonstrate the Applicant has made a generic invention that achieves the claimed result and do so by showing that the Applicant has invented species sufficient to support a claim to the functionally defined genus. As a result, what the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above

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are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

112 SECOND PARAGRAPH REJECTIONS

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 26-28 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26-28 and 81: The claims as written are ambiguous because it is unclear what ligands for a G-protein coupled receptor (see claim 26, line 10) Applicant is claiming that is compatible with the instant invention.

102 REJECTION

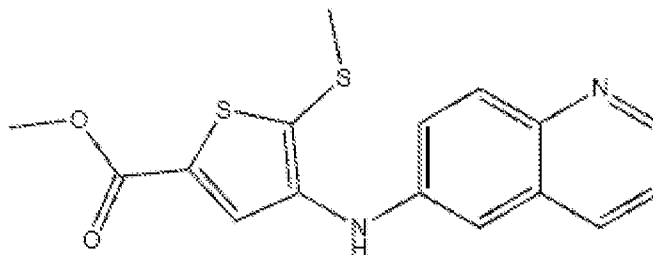
9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 26 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Illig et al (WO 00/47578).

Illig et al disclose heteroaryl amidines, methyl amidines, and guanidines that may be used as protease inhibitors (see entire document, especially, abstract). In particular, Illig et al disclose Example 197(a) which is directed to the formation of methyl-5-methylthio-4-(6-quinolylamino)thiophene-2-carboxylate (page 225, lines 4-22).



The structure of Example 197(a) is

Thus, both Applicant and Illig et al disclose a species encompassed by Applicant's Formula C wherein R = H; n = 0; m = 0; L = quinolyl; and Z = substituted 2-(carboxyl)heteroaryl group. Hence, the inventions disclose overlapping subject matter.

COMMENTS/NOTES

11. It should be noted that prior art has not been cited against claims 27 and 28.

However, the claims are rejected for 112 issues. In addition, it should be noted that the claims are only allowable as it relates to Applicant's elected species and the species of Illig et al cited in the rejection above. Specifically, the prior art neither anticipates nor renders obvious Applicant's radiolabeled elected species or the radiolabeling of the compound of Illig et al.

12. It should be noted that the full scope of the elected invention has not been search because prior art was found which could be used to reject the claims.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571)272-0617.

The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

March 17, 2011